

REMARKS/ARGUMENTS

The rejections presented in the Office Action dated November 9, 2005 (hereinafter Office Action) have been considered. Claims 1-48 and 80-100 remain pending in the application. Reconsideration of the pending claims and allowance of the application in view of the present response is respectfully requested.

The disclosure is objected to because serial numbers were missing from commonly owned patents in the following paragraphs: 41, 42, 45, 140 and 193. The specification has been amended to include serial numbers of the patent applications incorporated by reference.

Claim 15 stands rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the Applicants regard as their invention.

Applicants respectfully assert that claim 15 is in compliance with 35 U.S.C. § 112, second paragraph. The language of claim 15 defines patentable subject matter that meets the standard of *reasonableness* in degree of clarity and particularity. Moreover, claim 15 is sufficiently definite when analyzed in light of Applicants' disclosure, the teachings of the prior art, and the claim interpretation that would be given by one possessing the ordinary level of skill in the art at the time the invention was made. (MPEP 2173.02)

Claim 15 is directed to predicting that disordered breathing will occur and verifying that the disordered breathing actually did occur. Applicants assert that one skilled in the art would understand that after prediction of an event, the event may or may not occur. Verifying involves determining whether the predicted disordered breathing did or did not occur. Applicants respectfully disagree that "naturally the values would support the prediction," as asserted by the Examiner, because if the predicted event did not occur, the values may not support the prediction. Applicants assert that the claim language of claim 15 meets the standard of reasonableness and requests that the rejection under 35 U.S.C. §112, second paragraph be withdrawn.

Claims 1-9, 14-18, 22-34, 37, 39-42, 45, 47-48, 80-83, 85-86, 88-96, 98 and 100 stand rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Publication No. 2002/0193697 by *Cho et al.* (hereinafter "Cho"). Claims 1-9, 14-18, 22-27, 30-34, 37, 39-

48, 80-83, 85-86, 88-96, 98 and 100 stand rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent 6,928,324 to *Park et al.* (hereinafter “Park”).

Applicants respectfully disagree with the Examiner’s characterization of Cho and Park and the contention that either Cho or Park anticipates these claims. Applicants respectfully assert that several features recited in the claims are not disclosed in Cho or Park.

To anticipate a claim, the asserted reference must teach every element of the claim. A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. The identical invention must be shown in as complete detail as is contained in the claim. All claim elements, and their limitations, must be found in the prior art reference to maintain a rejection based on 35 U.S.C. §102.

Each of Applicants’ independent claims 1, 80, and 100 includes in some form predicting disordered breathing and delivering therapy to mitigate the predicted disordered breathing. Neither Cho nor Park teach or suggest that disordered breathing is predicted. Both of these references teach detecting presently occurring disordered breathing episodes.

The definition of the word predict is to “say or estimate that a specified thing will happen in the future.” *The New Oxford American Dictionary*, Oxford University Press, 2001. In one example, Applicants’ invention may be applied to sleep apnea. Patients with sleep apnea syndrome may experience disordered breathing during sleep sometimes hundreds of times per night for a minute or longer. (See page 2 lines 1-5 of the instant specification). Claims 1, 80, and 100 are directed to predicting the breathing that is disordered.

The approaches taught in Cho and Park do not describe predicting periods of disordered breathing that will happen in the future. Both Cho and Park teach detection of presently or prior occurring disordered breathing events rather than prediction of future disordered breathing.

For example, Cho teaches detection of presently occurring sleep apnea episodes. See, for example Cho, Figure 4, element 410 labeled “Detect Sleep Apnea.” See also, page

5, paragraph 43, of Cho “the sensor device 210 gathers various data from the patient to *detect* (at 410) sleep apnea.”

Park also teaches detection of presently occurring sleep apnea episodes. Park’s device is configured to “prevent, detect, and terminate sleep apnea.” (col. 6 lines 34-36) Prevention of sleep apnea is performed “by pacing at a rate that is greater than the patient’s intrinsic rate while sleeping.” (col. 6 lines 2-3). The high rate pacing as described by Park is performed without any prediction that disordered breathing will occur during sleep. Park also describes that the device may “detect episodes of sleep apnea using the physiological sensor and invoke treatment for sleep apnea.” (col. 6 lines 41-42) Thus, in contrast to Applicants’ invention, Park teaches 1) therapy delivery only after detecting that sleep apnea episodes are occurring, or 2) preventative therapy and does not teach delivering therapy based on prediction of the disordered breathing episodes.

Neither Park nor Cho teach all of the elements of Applicants’ independent claims 1, 80, and 100, including, for example, prediction of disordered breathing or delivering therapy based on the predicted disordered breathing. Thus, independent claims 1, 80, and 100 are not anticipated by Park or Cho and these claims are in condition for allowance.

Claims 2-9, 14-18, 22-34, 37, 39-48, 81-83, 85-86, 88-96, and 98 were also rejected under 35 U.S.C. §102(e) as being anticipated by Cho or Park. While Applicants do not acquiesce with the particular rejections to these dependent claims, it is believed that these rejections are now moot in view of the remarks made in connection with independent claims 1 and 80. These dependent claims include all of the limitations of the base claim and any intervening claims, and recite additional features which further distinguish these claims from the cited references. Dependent claims 2-9, 14-18, 22-34, 37, 39-48, 81-83, 85-86, 88-96, and 98 are not anticipated by Cho or Park and are also in condition for allowance.

Claims 19-21, 35-36, 38, 84 and 97 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Cho or Park.

Claims 19-21 are directed to time intervals within which the disordered breathing is predicted to occur. The Examiner contends that predicting disordered breathing will occur within certain time intervals is obvious in view of Cho and Park because these time intervals are optimum or workable ranges. Applicants respectfully disagree.

Neither Cho nor Park describe predicting disordered breathing and further do not describe predicting that the disordered breathing will occur within any particular time interval. The analysis of an optimum or workable range does not apply to these claims. *Aller* states: "it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 104 USPQ 233, 235 Prediction that a medical event is going to occur within a particular time interval does not reflect an "optimum or workable" range discovered by "routine experimentation."

Furthermore, Cho and Park are directed to therapy based on the detection of disordered breathing that is presently occurring or that has previously occurred. Neither teach predicting that disordered breathing is going to occur within a particular time interval and delivering therapy to mitigate or prevent the disordered breathing event that is predicted to occur. Because Applicants' invention is capable of delivering therapy based on the prediction of disordered breathing within a particular time interval, the patient need not receive therapy continuously, or after the disordered breathing has begun, but can receive therapy during a period just prior to the predicted interval of disordered breathing. This approach allows for more effective delivery of therapy to prevent or mitigate intervals of disordered breathing, without subjecting the patient to continuous therapy. Claims 19-21 are not anticipated or rendered obvious by the teachings of Cho or Park

Claim 35 is directed to calculating an estimated accuracy for a set of prediction criteria and adjusting the set of prediction criteria based on the estimated accuracy. Claim 36 is directed to calculating an estimated sensitivity for a set of prediction criteria and adjusting the set of prediction criteria based on the estimated sensitivity. Claim 38 is directed to deleting a particular set of prediction criteria from one or more sets of prediction criteria formed.

The Examiner contends that it would have been obvious to modify the criteria as taught by Cho and Park to include these features.

Neither Cho nor Park describe or suggest adjusting disordered breathing prediction criteria and further do not describe or suggest adjustment based on accuracy, sensitivity, or any other parameter. Furthermore these references do not teach deleting certain prediction criteria from one or more sets of criteria. It appears that the Examiner has taken official

notice of these limitations. Applicants respectfully assert that a fully or partially implantable method or device that predicts disordered breathing using sets of criteria that are adjusted based on sensitivity or accuracy, or that may be deleted are not facts that are “capable of instant and unquestionable demonstration as being well known or obvious to one skilled in the art” as required for official noticed facts. The ability to adjust the prediction criteria or delete certain sets of prediction criteria as set forth in these claims allows for an adaptive system that is not described or taught by Cho or Park and which has distinct advantages over the approaches taught by the asserted references.

Claim 84 is directed to a medical device for predicting disordered breathing and providing therapy to mitigate the disordered breathing that includes a patient-external sensor. Neither Cho nor Park teach a patient-external sensor. The Examiner asserts that it would have been obvious to modify Cho or Park with an external sensor because external sensors are less invasive. It appears that the Examiner is impermissibly taking official notice that the elements of Applicants’ claim 84, in view of Cho or Park references, constitute facts outside of the record which are capable of instant and unquestionable demonstration as being well known or obvious to one skilled in the art. Applicants disagree. The use of a patient external sensor in conjunction with an implantable or partially implantable system for the prediction of disordered breathing events is non-obvious in view of Cho or Park.

Claim 97 is directed to delivering therapy that is adapted to extend the device service life. Neither Cho nor Park describe the limitations of a therapy device for delivering disordered breathing therapy that is adapted to extend the device service life. The Examiner asserts that this limitation is obvious. Applicants assert that adapting the disordered breathing therapy delivered to mitigate predicted disordered breathing to extend the device service life is not a fact that is so well known as to “defy dispute” as required by MPEP § 2144.03.

It would appear that the Examiner is impermissibly taking official notice that the elements of Applicants’ claims 19-21, 35-36, 38, 84, and 97, in view of the Cho or Park references, constitute facts outside of the record which are capable of instant and unquestionable demonstration as being well known or obvious to one skilled in the art.

Applicants respectfully assert that the officially noticed facts do not constitute facts outside of the record which are capable of instant and unquestionable demonstration as being “well-known” in the art. The references relied on by the Examiner, for example, fail to disclose these purportedly “well known” facts. Applicants disagree with the Examiner’s exercise of official notice, and request that the Examiner provide evidence that supports the Examiner’s assertion that these claims are obvious pursuant to MPEP § 2144.03. Applicants reserve the opportunity to respond to the Examiner’s comments concerning any such officially noticed facts.

Claims 10-13 and 87 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Cho or Park in view of U.S. Patent No. 6,398,728 to *Bardy* (hereinafter “Bardy”). Claims 43-44, 46 and 99 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Cho in view of U.S. Patent No. 6,272,377 to *Sweeney et al.* (hereinafter “Sweeney”).

Three criteria must be met to establish a *prima facie* case of obviousness. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference. Second, there must be a reasonable expectation of success. Finally, the prior art reference, or combination of references, must teach or suggest all the claim limitations. MPEP § 2142.

Regarding the third criteria for *prima facie* obviousness set forth above, the references relied on by the Examiner do not teach or suggest all the limitations of Applicants’ claims. Each of the rejected claims depends from claims 1 or 80 and includes all of the limitations of the base claim from which the rejected claim depends along with additional limitations. Applicants reassert arguments presented above regarding the failure of Cho and Park to teach all of the limitations of claims 1 and 80. Neither Bardy nor Sweeney overcome the deficiencies of Cho and Park to teach or suggest the missing limitations of claims 1 and 80. Therefore, the combinations of references do not teach all of the limitations of Applicants’ rejected claims that depend from claims 1 or 80.

Furthermore, Applicants respectfully assert that the teachings of Cho or Park and Bardy or Cho or Park and Sweeney would provide insufficient guidance for one of ordinary skill in the art having these references before him/her to make the combination or

modifications suggested by the Examiner. Applicants respectfully assert that the Examiner's conclusion of obviousness is, instead, based on improper hindsight reasoning using knowledge gleaned only from Applicants' disclosure.

Claims 10-13, 43-44, 46, 87 and 99 are dependent from claims 1 or 80. Claims 1 and 80 are non-obvious under 35 U.S.C. 103, and any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988). While Applicants do not acquiesce with the particular rejections to these dependent claims, it is believed that these rejections are now moot in view of the remarks made in connection with independent claims 1 and 80. Applicants reserve the opportunity to present additional arguments that address these rejections more specifically if the rejections are maintained.

Claims 1-48 and 80-100 stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-97 of copending Application No. 10/643,203. Claims 1-48 and 80-100 stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-27 and 33-96 of copending application no. 10/642,998 in view of U.S. Patent No. 6,928,324 to *Park et al.* (hereinafter "Park"). Claims 1-48 and 80-100 stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-102 of copending application no. 10/643,016 in view of Park.

Applicants respectfully assert that, in view of arguments made above, the Examiner is compelled to withdraw the substantive art rejections of the claims. Once withdrawn, the only rejection remaining in the subject application is the provisional obviousness-type double patenting rejections. In view of MPEP § 804 I(B), Applicants respectfully request that the provisional obviousness-type double patenting rejections be withdrawn and that the subject application be permitted to issue as a patent.

It is to be understood that Applicants do not acquiesce to Examiner's characterization of the asserted art or Applicants' claimed subject matter, nor of the Examiner's application of the asserted art or combinations thereof to Applicants' claimed subject matter. Moreover, Applicants do not acquiesce to any explicit or implicit statements or conclusions by the Examiner concerning what would have been obvious to one of ordinary skill in the art, obvious design choices, alternative equivalent arrangements,


common knowledge at the time of Applicants' invention, officially noticed facts, and the like. Applicants respectfully submit that a detailed discussion of each of the Examiner's rejections beyond that provided above is not necessary, in view of the clear absence of teaching and suggestion of various features recited in Applicants' pending claims. Applicants, however, reserve the right to address in detail the Examiner's characterizations, conclusions, and rejections in future prosecution.

If the Examiner believes it necessary or helpful, the undersigned attorney of record invites the Examiner to contact her at to discuss any issues related to this case.

Respectfully submitted,

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